

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
(REV. 2-2005)

ATTORNEY'S DOCKET NUMBER

976-28 PCT/US

TRANSMITTAL LETTER TO THE UNITED STATES

DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/540296

INTERNATIONAL APPLICATION NO.  
PCT/CU2003/000020

INTERNATIONAL FILING DATE  
December 22, 2003

PRIORITY DATE CLAIMED  
December 27, 2002

TITLE OF INVENTION

FORMULATIONS FOR THE RECTAL ADMINISTRATION OF THROMBOLYTICALLY-ACTIVE AGENTS

APPLICANT(S) FOR DO/EO/US

Miragaya, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. EL 867445175 US
23. ☒ Other items or information:

Form PCT/1B/332  
Form PCT/1B/304

**EXPRESS MAIL CERTIFICATE**

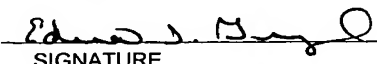
Date 02/10/03 Label No. EL867445175US  
I hereby certify that on the date indicated above,  
I deposited this paper or fee with the US Postal  
Service and that it was addressed for delivery to  
the Commissioner for Patents, PO Box 1450,  
Alexandria, VA 22313-1450 by EXPRESS  
MAIL, Post Office to Addressee Service.

PCTUS1/REV06

Name (Print)

Signature

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/540296</b>		INTERNATIONAL APPLICATION NO. <b>PCT/CU2003/000020</b>		ATTORNEY'S DOCKET NUMBER <b>976-28 PCT/US</b>	
The following fees are submitted:				<b>CALCULATIONS</b>	<b>PTO USE</b>
24. <input checked="" type="checkbox"/> Basic national fee		\$300		\$	\$300.00
25. <input checked="" type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4).		\$100		\$	\$200.00
All other situations.		\$200			
26. <input checked="" type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority		\$100			
International Search Report prepared and provided to the Office		\$400		\$	\$400.00
All other situations.		\$500			
<b>TOTAL OF 24, 25 and 26 =</b>				\$	\$900.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0 /50 =	0	x \$250.00	\$	\$0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	20 - 20 =	0	x \$50.00	\$	\$0.00
Independent claims	3 - 3 =	0	x \$200.00	\$	\$0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/>			+ \$360.00	\$	\$0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	\$900.00
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	\$450.00
<b>SUBTOTAL =</b>				\$	\$450.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	\$0.00
<b>TOTAL NATIONAL FEE =</b>				\$	\$450.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$	\$0.00
<b>TOTAL FEES ENCLOSED =</b>				\$	\$450.00
				Amount to be	\$
				Amount to be	\$
<p>a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>\$450.00</u> to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-2461</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
<p><b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p><b>Hoffmann &amp; Baron LLP</b> 6900 Jericho Turnpike Syosset, NY 11791</p> <p>CUsermer No.: 23869</p>					
				<p> SIGNATURE</p> <p><b>Edna I. Gergel, Ph.D.</b> NAME</p> <p><b>50,819</b> REGISTRATION NUMBER</p>	